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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,014	03/05/2001	Chad Stephen Gephart	209960.0004/1U3	5209
570	7590	07/09/2004	EXAMINER	
AKIN GUMP STRAUSS HAUER & FELD L.L.P. ONE COMMERCE SQUARE 2005 MARKET STREET, SUITE 2200 PHILADELPHIA, PA 19103-7013			OLSEN, KAJ K	
			ART UNIT	PAPER NUMBER
			1753	

DATE MAILED: 07/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/800,014

Applicant(s)

GEPHART ET AL.

Examiner

Kaj K Olsen

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*eo*

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18, 21 and 24-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18, 21 and 24-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: 4-19-2004.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-12, 17, 18, 21, 24, 26-28, 30 and 35-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks (USP 5,096,669) in view of Patko et al (USP 6,153,085). Patko is being cited for the first time with this office action.

1. Lauks disclosed all the limitations of the set forth system (see rejection of 9-11-2003), but did not explicitly set forth an indicia unique for each test cell, nor did Lauks set forth a reader for the indicia. Patko teaches in an alternate electrochemical sensor that a barcode can be utilized for storing information about the electrochemical device and that each barcode should be unique for that electrochemical sensor (col. 10, lines 48-56). The barcode of Patko allows more information to be transmitted to the instrument than can be transmitted by the notches of Lauks including calibration and quality control information and whether the sensor has been previously inserted into the instrument (col. 10, lines 48-56). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Patko for the system of Lauks in order to transmit more information about the test cell to the instrument including whether the strip has been previously inserted into the sensor. This is particular relevant to the teaching of Lauks, which is drawn to a sensor that is meant to be utilized once and discarded (see the title and the last sentence of the abstract). Preventing the reuse of the test strip would potentially prevent a false analysis of a patient's blood.

2. With respect to the various dependent claims, see the rejection of 9-11-2003.

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3. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks and Patko in further view of Tomita (USP 4,797,188).

4. Lauks and Patko teach all the limitations of the claims, but do not explicitly provide the detailed structure for the test cell. Tomita teaches in an alternate cell for monitoring the constituents in aqueous samples that a typical test cell for measuring concentrations of things such as potassium includes an electrolyte (i.e. an internal solution) 19 coated over one of the electrodes (fig. 1). Internal solutions are a well established means for ensuring appropriate electrochemical contact between the metal electrode and the sample and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Tomita for the system of Lauks and Patko in order to ensure appropriate electrochemical contact between the metal electrode and the sample. Tomita also teaches the use of a gelled form of the internal solution as well as an ion selective membrane 20 which has been impregnated with an appropriate chemical species over that gelled solution (col. 4, line 62 through col. 5, line 38).

5. Claims 25 and 29 (and claims 27 and 28 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks and Patko in further view of Jakubowicz et al (USP 4,798,705).

6. Lauks and Patko set forth all the limitations of the claims, but did not explicitly set forth the use of either a liquid crystal display or a thermal printer. Jakubowicz discloses that both those forms displays and printers are well known in the analytical art (col. 3, lines 3-6). With respect to claims 27 and 28 in the alternative), Jakubowicz also shows that the printer and keyboard of a system can be integrated into the instrument (fig. 1). It would have been obvious

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to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Jakubowicz for the system of Lauks and Patko because the substitution of one known means for display or printer for another known means requires only routine skill in the art.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Jakubowicz for the system of Lauks and Patko because integrating the keyboard and printer into the single device simplifies the system making it easier to handle.

7. Claims 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lauks and Patko in further view of Betts et al (USP 5,405,510).

8. Lauks and Patko set forth all the limitations of the claims, but did not explicitly identify the use of the RS 232 interface or the use of an internal power source. Betts discloses that both that particular interface as well as the use of batteries is well known in the art (col. 14, lines 6-9 and col. 19, lines 15-18). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Betts for the system of Lauks and Patko because the use of standard interfaces and power sources requires only routine skill in the art. With respect to the batteries being rechargeable, rechargeable batteries are an obvious and conventional form of battery and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize them because they would save the system operator money over the long term.

***Response to Arguments***

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 6:30 A.M. to 4:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kaj Olsen Ph.D.  
Primary Examiner  
AU 1753  
July 7, 2004